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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,740	12/05/2001	Alexander MacGregor	23936-176	2553

4372 7590 04/16/2007

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
04/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/006,740	**Applicant(s)** MACGREGOR, ALEXANDER	
	Examiner Blessing M. Fubara	**Art Unit** 1618	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 January 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☒ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 3. NOTE: The new recitation in claim 40 that the enteric coat partially surrounds the hydrostatic delivery system is new matter. Zero order release kinetics occurs over a "therapeutically practical time period (paragraph [0057]) or over 16 hours (paragraph [0105]) and deleting the phrase of "over a therapeutically practical time period" in claims 1 and 37 appears to extend the zero order release over time that is not supported by the specification as originally filed. The claims are directed to product comprising 38 a), b) and c); the prior art Dresdner discloses a composition that comprises hydrodynamic fluid imbibing polymer (CARBOPOL) and hydrostatic pressure modulating agent (cross-linked polyvinylpyrrolidone) and active agent as described in the office action of 11/13/06 in response to applicant's argument. Thus, with respect to applicant's argument regarding zero order vs. first order release, it is noted that the order of release is a characteristic of the composition and same compositions must necessarily have the same properties or characteristic. Dresdner discloses the composition/products of claims 38 and 39 and thus described all the limitations of the claims. Regarding applicant's argument that the combination of Rork and Conte does not teach all the limitations of the claims, it is noted that the carbopol and polyvinylpyrrolidone of Rork represents the hydrostatic couple, the active agents represent the agent of interest of the claims, the deficiency of Rork, which is the crosslinked polyvinylpyrrolidone is supplied by Conte, the motivation to combine the two references flows from the teaching that polyvinylpyrrolidone and cross-linked polyvinylpyrrolidone are combined with ranitidine in both arts to effect delivery of the ranitidine, so that using one polymer in place of the other will reasonably effect the release of the ranitidine. The layer containing the active agent, the Carbopol and the polyvinylpyrrolidone is homogeneous.

Continuation of 11. does NOT place the application in condition for allowance because: CARBOPOL 971P is a specific hydrodynamic Fluid-Imbibing Polymer(s) and crospovidone is a specific hydrostatic pressure modulating agent. It is noted that applicant's specification at paragraphs [0021]-[0031], [0064]- [0077] and [0078]- [0080] lists other polymers that are hydrodynamic and hydrostatic. Furthermore, applicant refers to examples 2-8, all of which describe CARBOPOL (hydrodynamic fluid-imbibing polymer) and crospovidone (hydrostatic pressure modulating agent) for which applicant has calculated ratio as presented. However, these ratios do not apply to all hydrodynamic fluid-imbibing polymer and all hydrostatic pressure modulating agent. Ratios of 35: 1; 50:1, 47.5:1, 132:1 and 167:1 as calculated by applicant and presented in the response after final does not represent all points in the claimed range of ratios of from 35:1 to 167:1. Similarly, the ratios calculated for the hydrodynamic fluid-imbibing polymer to agent do not represent all points in the claimed range of from 1:1 to about 9:1. There is thus no description for the claimed range in the new claim presented on 8/28/06.

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER